



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2023-0225; FRL-10919-01-OCSP]

RIN 2070-ZA16

O-Benzyl-P-Chlorophenol (OBPCP); Exemption from the Requirement of a Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to exempt residues of the antimicrobial pesticide ingredients Ortho-benzyl-para-chlorophenol, Potassium 2-benzyl-4-chlorophenate, and Sodium 2-benzyl-4-chlorophenate from the requirement of a tolerance when used on or applied to food contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils. This rulemaking is proposed on the Agency's own initiative under the Federal Food, Drug, and Cosmetic Act (FFDCA), in order to implement the tolerance actions EPA identified during its review of these chemicals as part of the Agency's registration review program under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2011-0423, by one of the following methods:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC),

(28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Anita Pease, Antimicrobials Division (7510M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 566-0736; email address: pease.anita@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are a pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI*. Do not submit this information to EPA through <https://www.regulations.gov> or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-

ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. Tips for preparing your comments. When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>.

II. Background

A. What action is the Agency taking?

EPA is proposing to establish exemptions from the requirement of a tolerance for residues of the antimicrobial pesticides Ortho-benzyl-para-chlorophenol, Potassium 2-benzyl-4-chlorophenate, and Sodium 2-benzyl-4-chlorophenate on food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils. EPA is proposing these exemptions to cover residues of Ortho-benzyl-para-chlorophenol, Potassium 2-benzyl-4-chlorophenate, and Sodium 2-benzyl-4-chlorophenate that may be found in food as a result of the use of these antimicrobials on food-contact surfaces. This tolerance exemption will supersede the current exemption for Ortho-benzyl-para-chlorophenol under 40 CFR 180.940(c), which is listed as Phenol, 4-chloro-2-(phenylmethyl)-, an alternative name for Ortho-benzyl-para-chlorophenol. The current exemption limits the end-use concentration of this substance to 320 ppm in end-use antimicrobial solutions. Upon establishment of the new exemption, EPA intends to remove the existing exemption as it would be unnecessary and redundant.

EPA is proposing these tolerance actions to implement the tolerance changes identified as necessary during the registration review processes to cover these pesticide chemical residues when used in antimicrobial formulations consistent with current label use directions. Registration review documents, such as the draft risk assessment, typically identify certain tolerance actions, including modifications to reflect current use patterns, meet safety findings, and change commodity names and groupings, that may be necessary or appropriate to cover pesticide

chemical residues or reflect current EPA policy.

For the pesticide chemicals at issue in this rulemaking, EPA issued the “O-Benzyl-p-Chlorophenol (OBPCP) Interim Registration Review Decision” (OBPCP ID) in November 2019. Electronic copies of the OBPCP ID and other documents are available in EPA docket number EPA-HQ-OPP-2011-0423, which can be found at <https://www.regulations.gov>. EPA’s risk assessment for OBPCP contains the Agency’s assessment of the potential risk associated with current product uses, and based on the findings of that risk assessment, the OBPCP ID identified the need to establish exemptions from the requirement of a tolerance for Ortho-benzyl-para-chlorophenol, Potassium 2-benzyl-4-chlorophenate, and Sodium 2-benzyl-4-chlorophenate on food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils.

B. What is the Agency’s authority for taking this action?

Section 408(e) of the FFDCA authorizes EPA to establish exemptions from the requirement of a tolerance. 21 U.S.C. 346a(e)(1)(B). Before issuing the final exemption, EPA is required to issue a proposed rulemaking and provide a comment period. *Id.* at 346a(e)(2).

A “tolerance” represents the maximum level for residues of pesticide chemicals legally allowed in or on raw agricultural commodities and processed foods. Section 408 of FFDCA, 21 U.S.C. 346a, authorizes the establishment, modification, and revocation of tolerances and exemptions from the requirement of a tolerance for residues of pesticide chemicals in or on raw agricultural commodities and processed foods. Residues of pesticides in or on food that are not covered by a tolerance or exemption are deemed unsafe, 21 U.S.C. 408(a), and any food containing unsafe residues is considered adulterated under FFDCA section 402(a), 21 U.S.C. 342(a). Such food may not be distributed in interstate commerce, 21 U.S.C. 331(a). For a food-use pesticide to be sold and distributed, the pesticide must not only have appropriate tolerances under the FFDCA but also must be registered under FIFRA, 7 U.S.C. 136 *et seq.* Moreover, residues of food-use pesticides not registered in the United States must also be covered by a U.S.

tolerance or exemption in order for commodities treated with those pesticides to be imported into the United States.

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(c)(2)(A)(ii) of the FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” 21 U.S.C. 346a(c)(2)(A)(ii). This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(c)(2)(B) of the FFDCA requires EPA, when making a safety determination concerning an exemption, to take into account, among other relevant considerations, the considerations listed in section 408(b)(2)(C) and (D) of the FFDCA. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....” Section 408(b)(2)(D) identifies various factors, including available information on aggregate and cumulative exposure, for EPA consideration in making a safety determination.

C. When do these actions become effective?

EPA is proposing that these tolerance actions become effective on the date of publication of the final rule in the *Federal Register*.

III. Proposed Rule

EPA is proposing this rule to implement the tolerance actions identified in the OBPCP ID. As noted in the November 2019 OBPCP ID, there is an exemption from the requirement of a tolerance under 40 CFR 180.940(c) for residues of Ortho-benzyl-para-chlorophenol resulting from applications to food-processing equipment and utensils, with the limitation that the end-use

concentration of Ortho-benzyl-para-chlorophenol does not exceed 320 ppm. During registration review, EPA determined that Ortho-benzyl-para-chlorophenol, Potassium 2-benzyl-4-chlorophenate, and Sodium 2-benzyl-4-chlorophenate were also registered for use in public eating areas and on dairy-processing equipment, as well as at a higher rate on food-processing equipment and utensils; therefore, there is a need to establish additional exemptions for residues resulting from these registered uses. EPA, on its own initiative, is proposing to establish the necessary exemptions under 40 CFR 180.940(a), which would cover all food-contact uses of Ortho-benzyl-para-chlorophenol, Potassium 2-benzyl-4-chlorophenate, and Sodium 2-benzyl-4-chlorophenate pesticide products, when used in antimicrobial formulations not to exceed a concentration of 2,080 ppm in the end-use formulation. When established, the 180.940(a) exemption will supersede the current exemption in 40 CFR 180.940(c) for registrations containing Ortho-benzyl-para-chlorophenol up to 320 ppm used on food processing equipment and utensils.

In order to establish tolerances or exemptions from the requirement of a tolerance, EPA is required to determine that each tolerance or exemption meets the safety standard of FFDCA. In its risk assessment supporting the OBPCP ID, EPA considered the potential risks from exposure to Ortho-benzyl-para-chlorophenol, Potassium 2-benzyl-4-chlorophenate, and Sodium 2-benzyl-4-chlorophenate from registered uses and concluded that those uses did not present risks of concern. *See* U.S. EPA, Registration Review Draft Risk Assessment for: O-Benzyl-P-Chlorophenol (OBPCP) and Salts (OBPCP DRA), available at <https://www.regulations.gov> in docket ID number EPA-HQ-OPP-2011-0423.

A. Aggregate Risk Assessment and Determination of Safety

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure to support the establishment of exemptions from the requirement of a tolerance for residues of Ortho-benzyl-para-chlorophenol,

Sodium 2-benzyl-4-chlorophenate, and Potassium 2-benzyl-4-chlorophenate.

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime.

EPA's risk assessment Ortho-benzyl-para-chlorophenol, Potassium 2-benzyl-4-chlorophenate, and Sodium 2-benzyl-4-chlorophenate can be found in full at <https://www.regulations.gov> in docket ID number EPA-HQ-OPP-2011-0423. That document explains EPA's analysis of the toxicity of the pesticide chemicals as well as the selection of toxicological points of departure and levels of concern for use in evaluating the risk posed by human exposure to the pesticide. In addition, that document is based on the maximum label rate for commercial use.

The Agency did not identify any dietary or aggregate risks of concern for Ortho-benzyl-para-chlorophenol, Sodium 2-benzyl-4-chlorophenate, and Potassium 2-benzyl-4-chlorophenate

during the risk assessment.

Based on the lack of any aggregate risks of concern, EPA concludes that these exemptions from the requirement of a tolerance for residues of Ortho-benzyl-para-chlorophenol, Sodium 2-benzyl-4-chlorophenate, and Potassium 2-benzyl-4-chlorophenate, including the limitation for the end-use formulation concentration of each of these pesticides does not exceed 2,080 ppm, are safe, *i.e.*, there is a reasonable certainty that no harm will result from aggregate exposures to Ortho-benzyl-para-chlorophenol, Sodium 2-benzyl-4-chlorophenate, or Potassium 2-benzyl-4-chlorophenate, when used in accordance with the terms of the respective exemptions. In addition, EPA has determined that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residues, in accordance with FFDCA section 408(b)(2)(C).

B. Conclusion

Therefore, EPA is proposing to establish exemptions in 40 CFR 180.940(a) for residues of the antimicrobial pesticide ingredients Ortho-benzyl-para-chlorophenol, Potassium 2-benzyl-4-chlorophenate, and Sodium 2-benzyl-4-chlorophenate from the requirement of a tolerance when used on or applied to food contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils, with a limitation in concentration of 2,080 ppm in end-use formulations. In addition, EPA is proposing to remove the existing exemption in 40 CFR 180.940(c) the exemption for Phenol, 4-chloro-2-(phenylmethyl)-, as it will be superseded by these new exemptions.

IV. Statutory and Executive Order Reviews

In this proposed rule, EPA is proposing to exempt residues of the antimicrobial pesticide ingredients Ortho-benzyl-para-chlorophenol, Potassium 2-benzyl-4-chlorophenate, and Sodium 2-benzyl-4-chlorophenate from the requirement of a tolerance when used on or applied to food contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils. This document is proposing to establish exemptions from the

requirement of a tolerance under FFDCA section 408(e), and also remove a specific exemption as no longer necessary. The Office of Management and Budget (OMB) has exempted these types of actions (*e.g.*, establishment and modification of a tolerance and tolerance revocation for which extraordinary circumstances do not exist) from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001). This proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*) or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*). Nor does it require any special considerations as required by Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994); or OMB review or any other Agency action under Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This proposed rule does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note). Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency previously assessed whether establishment of tolerances, exemptions from tolerances, raising of tolerance levels, expansion of exemptions, or revocations might significantly impact a substantial number of small entities and concluded that, as a general matter, these actions do not impose a significant economic impact on a substantial number of small entities. These analyses for tolerance establishments and modifications, and for tolerance revocations were published in the *Federal Register* of May 4, 1981 (46 FR 24950) and December 17, 1997 (62 FR 66020) (FRL-5753-1), respectively, and were provided to the Chief

Counsel for Advocacy of the Small Business Administration. Taking into account this analysis, and available information concerning the pesticides listed in this proposed rule, the Agency hereby certifies that this proposed rule will not have a significant negative economic impact on a substantial number of small entities. Furthermore, for the pesticide named in this proposed rule, the Agency knows of no extraordinary circumstances that exist as to the present proposed rule that would change EPA's previous analysis. Any comments about the Agency's determination should be submitted to the EPA along with comments on the proposed rule and will be addressed prior to issuing a final rule. In addition, the Agency has determined that this proposed rule will not have a substantial direct effect on States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999). Executive Order 13132, requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive order to include regulations that have "substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government." This proposed rule directly regulates growers, food processors, food handlers, and food retailers, not States. This proposed rule does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this proposed rule does not have any "tribal implications" as described in Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive order to include regulations

that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This proposed rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this proposed rule.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 1, 2023.

Edward Messina,

Director, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

**PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL
RESIDUES IN FOOD**

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.940:

a. Amend paragraph (a) the table by, adding in alphabetical order, the entries “Ortho-benzyl-para-chlorophenol”; “Potassium 2-benzyl-4-chlorophenate” and “Sodium 2-benzyl-4-chlorophenate”.

b. Amend paragraph (c) the table by removing the entry for “Phenol, 4-chloro-2-(phenylmethyl)-”.

The additions read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

* * * * *

Pesticide Chemical	CAS Reg. No.	Limits
* *	* * *	* *
Ortho-benzyl-para-chlorophenol	120-32-1	When ready for use, the end-use concentration is not to exceed 2080 ppm
* *	* * *	* *
Potassium 2-benzyl-4-chlorophenate	35471-49-9	When ready for use, the end-use concentration is not to exceed 2080 ppm
* *	* * *	* *
Sodium 2-benzyl-4-chlorophenate	3184-65-4	When ready for use, the end-use concentration is not to exceed 2080 ppm
* *	* * *	* *

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